IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF E. STANTON SHOEMAKER, M.D.

E. Stanton Shoemaker, M.D. is a board-certified obstetrician-gynecologist (OB-GYN) who has performed over 1,000 polypropylene mesh sling placements and pelvic organ prolapse (POP) reconstructions with mesh devices. He has also performed mesh revision surgeries. In addition, Dr. Shoemaker has educated and trained surgeons in mesh techniques and has reviewed the relevant medical literature related to the devices at issue in these proceedings.

Despite this extensive career, Plaintiffs seek to exclude Dr. Shoemaker's opinions about: (1) other physicians' knowledge relating to Instructions for Use (IFUs); (2) the adequacy of Ethicon's IFUs for TVT and POP devices; (3) physical properties of polypropylene, and (4) various "legal conclusions." Plaintiffs' motion should be denied because:

- **Dr. Shoemaker's training and experience amply support his opinions on physicians' knowledge.** Dr. Shoemaker is fit to testify about what other physicians knew as it relates to the standard of care for warnings for the TVT and POP devices.

- **Dr. Shoemaker is qualified to offer the challenged opinions, and he has fully supports them with a reliable basis.** Dr. Shoemaker's training, experience, and review of the relevant medical literature qualify him to offer opinions on the IFUs for the TVT and POP devices, as well as the physical properties of polypropylene. In addition, his extensive clinical experience and review of the peer-reviewed literature constitute a reliable methodology to reach these opinions.

- **Dr. Shoemaker's opinions are not inadmissible legal conclusions.** Dr. Shoemaker is entitled to offer the challenged expert testimony without using terms that state legal standards.

Plaintiffs' challenges to Dr. Shoemaker's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. Shoemaker's Training and Experience Support His Opinion on Physicians' Knowledge.

In *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 720-21 (S.D.W. Va. 2014), this Court held that plaintiffs' expert urologist, Dr. Blaivas, could offer opinions about what was known about mesh complications and warnings discussed by educators in lectures addressing the use of mesh for surgical treatment of stress incontinence. The Court concluded that, as a urologist, Dr. Blaivas was "certainly fit to testify what other physicians knew as it relates to the standard of care for designing a mesh product and warning about its potential risks." *Id.* at 721.

Dr. Shoemaker seeks to offer the same kind of opinion here. Dr. Shoemaker has been a board-certified OB-GYN for over 30 years. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker Gynemesh PS, Prolift, Prolift+M and Prosima (POP Device) Report at 1-2. He has specialized, in part, on the treatment of pelvic floor reconstruction and urinary incontinence. *Id.* at 2. He has performed more than 1,500 surgical procedures to treat POP and stress urinary incontinence (SUI), including site-specific defect repairs, native-tissue repair, and biologic grafts, in addition

to synthetic grafts. *Id.* at 4. In fact, he has performed over 1,000 polypropylene mesh sling placements and POP reconstructions with mesh devices. Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 36:18-38:6, 67:3-8. He also has performed between 12 and 20 transvaginal mesh revision surgeries. *Id.* at 20:16-23.

Because of his specialized knowledge and experience, Dr. Shoemaker often is asked to instruct other OB-GYNs in these techniques. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 2. He has served as a speaker and preceptor for surgeons at Ethicon-sponsored training sessions since the early 2000s. *Id.*; Ex. B to Pls.' Mot. (Dkt. 2104-2), Shoemaker Curriculum Vitae; Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 121:22-122:13. In those training sessions, he has demonstrated the proper way to implant Ethicon's TVT and POP devices, and also discussed information contained in the IFUs. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 2.

Dr. Shoemaker therefore is familiar with how physicians are trained and what information is provided with regard to mesh devices. *Id.* at 3. Based on his continuing medical education, review of medical literature, discussions with colleagues, attendance and participation in medical meetings, and teaching other physicians, he is familiar with how physicians obtain the information they rely upon in performing mesh techniques, as well as the way in which they keep themselves apprised of advances in medicine. *Id.*

With this background and experience as support, Dr. Shoemaker has opined about the general knowledge of surgeons who perform polypropylene mesh sling placements and POP reconstructions, as well as the types of information upon which they rely to learn about risks. *Id.* at 20, 23-25, 27, 35-37; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT and TVT-O Mid-Urethral Slings (TVT) Report at 20, 30-32. Just as Dr. Blaivas was "certainly fit" to testify about

what other physicians knew about risks of mesh complications and warnings provided by educators, *see Huskey*, 29 F. Supp. 3d at 721, Dr. Shoemaker is likewise in a position to provide a reliable assessment concerning what other physicians know about risks of pelvic-floor surgeries (including those using mesh devices), and the information upon which they rely to learn about such risks. Dr. Shoemaker's testimony about other physicians' knowledge therefore is admissible. *Id*.

II. Dr. Shoemaker's Opinions on the IFU Are Admissible Because He Is Qualified and Has Utilized a Reliable Methodology.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015). A doctor is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues).

Dr. Shoemaker seeks to offer such an opinion here. In addition to his clinical experience with mesh techniques and review of IFUs, Dr. Shoemaker relies on his review of complications reported in the medical literature, statements of leading medical societies, discussions with other surgeons, and his general knowledge as a pelvic-floor surgeon to render his opinions on warnings. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 1-7, 20-27, 32-36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 1-8, 13, 17-25, 30-32; Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 136:9-16, 137:19-138:5, 156:10-157:1. Based on this support, Dr. Shoemaker has formed the opinion that exposure, erosion, or

extrusion are the only unique risks of pelvic mesh, and that there is no reliable data that degradation, particle loss, roping, fraying, curling, and cytotoxicity occur. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 20-27, 32-36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 13, 17-25, 30-32; Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 156:10-157:1.

The risks of mesh exposure/erosion/extrusion have long been known to surgeons. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 23-24, 27; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 13, 20. Indeed, the original IFUs for POP and TVT devices warned of several risks including damage to vessels, nerves, bladder and bowel, inflammation, extrusion, and erosion. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 31. Further, Dr. Shoemaker explained that surgeons understand that these complications may cause pain and dyspareunia, as well as the need for additional surgery. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 31. Moreover, post-surgery dyspareunia and chronic pelvic pain are well-known risks of any pelvic surgery, as is erosion and wound complications from sutures used during SUI treatment, and therefore these side effects are not unique to pelvic mesh devices. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 25, 36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 13, 31.

From the standpoint of a clinician, Dr. Shoemaker has concluded that only those risks that are unique to the device, clinically significant, and make a difference in use of the device need be included in the device warnings. Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 135:16-24. Dr. Shoemaker's opinion is consistent with the legal principle that there is

no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (explaining that information may be omitted from labeling for prescription device "if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device"). Dr. Shoemaker thus opines there are no additional unique risks of the TVT and POP devices that should be included in the IFUs. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 20-27, 32-36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 13, 17-25, 30-32. Dr. Shoemaker's opinions are well-supported and should be deemed reliable.

This Court's rulings in *Tyree* and *Bellew* are distinguishable. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 584 (S.D.W. Va. 2014); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Dkt. 265 at 33 (S.D.W. Va. Nov. 20, 2014). While a single physician's experience may not be sufficient, it is sound methodology to rely upon a large pool of peer-reviewed scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that a risk does not occur and therefore need not be included in the IFU. Indeed, when plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings.

It stands to reason then that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Shoemaker's conclusion goes to weight, not admissibility. Dr. Shoemaker has used a reliable methodology to support his conclusion that risks other than mesh exposure/erosion/extrusion

either do not occur, are not clinically significant, or are risks of pelvic *surgery* well known to surgeons rather than the mesh *product*, and thus need not be included in the mesh warnings.

Based on his training and experience, Dr. Shoemaker is an expert in warnings from a clinical perspective. Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 136:1-8, 137:19-138:5. In his practice, Dr. Shoemaker has used several different medical devices and read many IFUs over the years. *Id.* at 136:9-16. Dr. Shoemaker also has performed over 1,000 polypropylene mesh sling placements and POP reconstructions with mesh devices as well as transvaginal mesh revision surgeries. *Id.* at 20:16-23, 36:18-38:6, 67:3-8. Dr. Shoemaker's opinion on the IFUs also is informed by his training of other physicians, attendance at professional meetings, and discussions with other physicians. *Id.* at 156:10-157:1. He need not be familiar with FDA rules or federal regulations to give this testimony. *Winebarger*, 2015 WL 1887222, at *6-7, 15; *see also Huskey*, 29 F. Supp. 3d at 703-04, 719 (Drs. Rosenzweig and Blaivas adequately experienced physicians to testify to risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *13-14 (S.D.W. Va. Apr. 28, 2016) (Dr. Shull permitted to testify on adequacy of DFUs "from a clinical perspective"). Plaintiffs' arguments to the contrary should be rejected.

At bottom, Dr. Shoemaker is qualified to provide opinions on the IFUs and has employed a sufficiently reliable methodology. His opinion on the adequacy of the TVT and POP device IFUs is therefore admissible.

III. Dr. Shoemaker's Opinions on Physical Properties of Polypropylene Are Admissible Because He is Qualified and He Has Utilized a Reliable Methodology.

A physician can be qualified by training and experience to provide opinions on the biocompatibility properties of pelvic mesh. *See, e.g.*, *Mathison v. Boston Scientific Corp.*, No.

2:13-CV-05851, 2015 WL 2124991, at *28 (S.D.W. Va. May 6, 2015). In *Mathison*, the plaintiffs sought to exclude the defendant's expert urologist from offering opinions relating to the physical properties of polypropylene, including shrinkage, contraction, and degradation, because the expert did not have pathology expertise. *Id*. The Court rejected the plaintiffs' argument, finding that the expert was qualified due to his experience performing thousands of sling procedures, and the literature cited throughout his expert report supporting his opinion that the mesh was safe and effective. *Id.*; *see also Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *5-6 (S.D.W. Va. Feb. 7, 2015) (allowing plaintiffs' expert in obstetrics, gynecology, and urogynecology to testify about the characteristics of polypropylene based on his performance of thousands of POP surgeries and reliance on peer-reviewed research); *Wilkerson v. Boston Scientific Corp*., No. 2:13-CV-04505, 2015 WL 2087048, at *5 (S.D.W. Va. May 5, 2015) (allowing plaintiffs' urogynecologist to testify about the biochemical properties of polypropylene based on his clinical experience and review of scientific articles).

Here too, Dr. Shoemaker has performed over 1,000 pelvic mesh procedures, and cites numerous articles and studies throughout his report demonstrating the safety and efficacy of Ethicon's mesh devices. *See, e.g*., Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 20-27, 35-36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 17-25, 30-32; Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 36:18-38:6, 67:3-8. Thus, contrary to Plaintiffs' argument, Dr. Shoemaker need not be a pathologist or biomaterials expert to render opinions on the physical properties of polypropylene. *Mathison*, 2015 WL 2124991, at *28 (concluding that a lack of personal experience performing pathology research on polypropylene explants did not render defense expert unqualified to testify about the physical properties of polypropylene); *see also Tyree*, 54 F. Supp. 3d at 585 (finding urologist with

extensive pelvic-floor surgical experience qualified to offer opinions about mesh properties even though urologist was not a pathologist); *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872, at *20 (S.D.W. Va. Jan. 15, 2014) (same, with respect to a urogynecologist with similar experience).

Additionally, the precise opinions that Plaintiffs seek to exclude relate primarily to the *clinical* aspects of mesh biocompatibility. *See* Pls.' Mem. (Dkt. 2105) at 6-8. These clinical aspects fit exactly within the expertise of Dr. Shoemaker, an OB-GYN who has performed thousands of pelvic surgeries with and without mesh, and treated patients experiencing complications. As this Court has recognized, an expert's own clinical observations serve as a valid basis to opine concerning alleged mesh defects. *Mathison*, 2015 WL 2124991, at *29. Further, "'[o]ne knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion.'" *Id*. at *28 (quoting *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989)).

Further, Dr. Shoemaker has provided a sufficient basis for his opinions. Dr. Shoemaker has reviewed the clinical data and literature, and has found no scientifically reliable evidence that polypropylene mesh degrades, results in particle loss, ropes, frays, curls, or increases the risk of cancer. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 20-34; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 13-25. As this Court has held, reliance on clinical experience combined with review of the medical literature constitutes a reliable methodology to support an opinion on the physical properties of polypropylene. *See, e.g.*, *Mathison*, 2015 WL 2124991, at *28; *Wise*, 2015 WL 521202, at *5-6; *Wilkerson*, 2015 WL 2087048, at *5; *Lewis*, 2014 WL 186872, at *20.

Accordingly, Dr. Shoemaker has the expertise required to provide opinions on the physical properties of Ethicon's mesh devices. And because he used a reliable methodology to form these opinions, this testimony is admissible.

IV. Dr. Shoemaker's Opinions Are Not Inadmissible Legal Conclusions.

This Court repeatedly has held that experts may not provide opinion testimony that states a legal standard, uses a legal term of art, or draws a legal conclusion by applying law to the facts—*e.g.*, "defective," "unreasonably dangerous," "not reasonably safe," "reasonable and prudent medical device manufacturer." *See, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013); *Winebarger*, 2015 WL 1887222, at *3; *Lewis*, 2014 WL 186872, at *21. However, "[a]n opinion is not objectionable just because it embraces an ultimate issue." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 629 (quoting FED. R. EVID. 704(a)). The Court has made it clear, therefore, that experts may offer general opinions about the safety of mesh products and warnings "using terms that do not have a separate, distinct, and specialized meaning in the law." *Id.*; *see also Lewis*, 2014 WL 186872, at *21 (expert opinions admissible but cannot be phrased as legal conclusions).

Dr. Shoemaker will not use impermissible legal terms of art in expressing his disclosed opinions at trial. His opinions about warnings, Ethicon's education and training of doctors, and his benefit-risk assessment for mesh products, however, are admissible so long as he avoids terms that have a specialized meaning in the law. As such, Plaintiffs' argument does not provide a basis to exclude Dr. Shoemaker's underlying opinions.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 16, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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